REMARKS

Claims 1-74 are pending in the application. Claims 31-45 have been withdrawn. Claims 56 and 57 have been rejoined by the Examiner as stated in the November 15, 2005, Office Action. Claims 11, 13, 16 and 18 are canceled. Claim 17 is amended to depend from claim 15, dependency to canceled claim 16 is deleted.

Substance of Interview

Applicants appreciate the Examiner's courtesy in allowing Applicants' Representatives to conduct a Personal Interview at the USPTO on July 25, 2006. During this Interview, Applicants submitted arguments traversing the rejection of claims 1, 53, 58, 59, 66 and 74 and claims depending therefrom under 35 USC §102(b).

The Examiner had rejected the above-cited claims in the present Office Action because she alleged that the inventive polynucleotides, which encode a chimeric glycoprotein incorporating "one or more heterologous structural domains, antigenic domains or epitopes of a second, antigenically distinct HPIV", are allegedly encompassed by Belshe (U.S. Patent 5,869,036). Belshe discloses "swapping" an entire glycoprotein from a JS wild-type genome with an entire glycoprotein from a cp45 genome. The Examiner has asserted a chimeric glycoprotein can result from this exchange, because switching the entirety of the F protein from JS wild type for the F protein of cp45 gives the same result as making a chimera of these two proteins.

Applicants explained that the JS wild-type virus and the cp45 virus are not "antigenically distinct", given the definition of this phrase as understood by a skilled artisan and therefore, Belshe does not disclose or suggest the present invention. Antibodies to each of these viruses are

cross-reactive with the other virus, and so the glycoproteins of JS and cp45 are not antigenically distinct. Thus, the instant claims are not encompassed by Belshe. The Examiner stated she would consider these arguments. In a follow-up teleconference on August 7, 2006, the Examiner stated that the rejection would be withdrawn providing Applicants state the ordinary meaning of the phrase "antigenically distinct" as understood by a skilled artisan in the Response to the Office Action.

Applicants also submitted arguments during the interview traversing the §112, first paragraph, rejection of claims 26 and 71 and claims depending therefrom. In the present Office Action, the Examiner rejected the claims for recitation of the genus "said partial or complete PIV genome or antigenome including a mutation encoding a substitution of amino acid 456 of the L protein by another amino acid", stating that the Applicants were not in possession of the claimed genus at the time of filing.

During the interview, Applicants stated that a skilled artisan is able to envision the 20 amino acids that may be located at position 456 of the L protein, therefore Applicants were in possession of the claimed genus. Moreover, Applicants stated that even if the rejection is more properly stated as an enablement rejection because it is not immediately clear what substitutions are operable, the rejection is still improper because a skilled artisan is amply guided by the specification to routinely determine which embodiments are operable.

The Examiner alleged that the specification does not disclose a nexus between the *type* of amino acid substituted (*e.g.* hydrophilic amino acids) and attenuation. However, Applicants submitted that the specification does disclose a nexus between the location of the amino acid substitution and attenuation. (See, *e.g.* page 57, line 8, through to page 58, line 8 in the specification as filed). The Examiner stated she would reconsider this rejection. In a follow-up teleconference on August 7, 2006, the Examiner agreed to withdraw the §112, first paragraph rejection.

Claim Rejection-35 USC § 112, first paragraph

Enablement

Claims 11,13 and 16-18 stand rejected under 35 USC §112, first paragraph, for failure of the specification to comply with the enablement requirement. Applicants believe that the specification completely enables making of viruses the same as those specifically named in the claims, as explained previously. However, to advance prosecution of this application, claims 11, 13, 16 and 18 are canceled. Claim 17 is amended to remove dependency from claim 16. Accordingly, the rejection is moot.

Written Description

Claims 26 and 71 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. As stated *supra*, the Examiner agreed on August 7, 2006, in a teleconference with Applicants' representatives to withdraw the rejection. Accordingly, this rejection is overcome.

Claim Rejections – 35 USC §102

Claims 1-10, 12, 19-23, 25, 28-30, 46-49, 53-59, 65, 66 and 74 stand rejected under 35 USC §102(e) as assertedly being anticipated by US Patent No. 5,869,036 to Belshe *et al.* ("Belshe"). Applicants respectfully traverse.

The present invention is drawn to an infectious chimeric parainfluenza virus (PIV) or isolated polynucleotide comprising a human PIV (HPIV) background genome or antigenome that is modified to encode a chimeric glycoprotein incorporating one or more heterologous structural domains, antigenic domains or epitopes of a second, antigenically distinct HPIV.

In contrast, Belshe discloses "swapping" an entire glycoprotein from a JS wild-type genome with an entire glycoprotein from a cp45 genome. Even if such a swap were to result in a chimeric glycoprotein as the Examiner asserts (see, page 8 in the present Office Action), the JS

wild-type virus and the cp45 virus are not "antigenically distinct." Two antigens are "antigenically distinct", as understood by a skilled artisan, if a first antigen induces the production of antibodies that do not specifically bind the second antigen, and vice-versa. Thus, the claimed chimeric glycoproteins contain domains or epitopes from a second HPIV, which induce antibodies that are not cross-reactive with antigens from the domains or epitopes from the background HPIV. Moreover, because the proteins of JS wild-type virus and its cp45 derivative are identical but for a few point mutations (10 are present among all the proteins of the virus), antibodies raised against one of these viruses will also specifically bind the other virus. Thus, the Belshe reference does not disclose the element of a "second, antigenically distinct HPIV."

Because a claim is anticipated only if each and every element as set forth in the claim is disclosed in a reference, the Belshe reference does not anticipate the claims. For the above reasons, independent claims 1, 53, 56, 58, 59, 66 and 74 and claims dependent thereon, are not anticipated by Belshe. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

Rejection for non-statutory double-patenting

09/083, 793

Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 144-215 of copending Application No. 09/083, 793.

Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

09/458, 813

Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of 53-83 of copending Application No. 09/458, 813.

Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

09/586, 479

Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 85, 88-92, 94-96, 98, 99, 101, 104, 107, 108, 113-117, 119, 122-126, 128-130, 132, 133, 135, 140, 141, 146-152, 154, 157, 159, 162 and 164 of copending Application No. 09/586,479.

Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

09/733, 692

Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of 180-222 of copending Application No. 09/733, 692.

Applicants submit herewith a Terminal Disclaimer, thereby obviating this ground of rejection.

Request for Rejoinder

Claims 31-45, directed to a method for stimulating the immune system of an individual, stand presently withdrawn from consideration. Applicants submit that, being ultimately dependent from claim 1, these claims are commensurate in scope with the presently allowable composition claims and represent methods of use of such compositions. As such, Applicants respectfully request that the Examiner rejoin claims 31-45 to the present application and promptly allow these claims, pursuant to examination practices set forth in MPEP § 821.04.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims and passage of the application to issue is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: August 18, 2006

Respectfully submitted,

By _____

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Attachment: Terminal Disclaimer